AUG 01 2002

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510(k) Summary of Safety & Effectiveness

Submitter	Vanguard Medical Concepts, Inc. 5307 Great Oak Drive Lakeland, FL 33815
Contact	Mr. Mike Sammon, Ph.D. Director, Research and Development (863) 683-8680, extension 228 (801) 327-3339 (facsimile) mikes@safe-reuse.com
Date	August 13, 2001
Device	• Trade Names: Vanguard Reprocessed Diagnostic Electrophysiology Catheters ⇒ Biosense Webster Diagnostic Electrophysiology Catheters • Common Name: Diagnostic Electrophysiology (EP) Catheter • Classification: 21 CFR 870.1220 – Class II – Electrode recording catheter or electrode recording probe • Product Code DRF
Predicate Devices	Biosense Webster and Bard Electrophysiology legally marketed diagnostic EP catheters under various 510(k) premarket notifications.
Indications for Use	This catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g. evaluation of arrhythmias or cardiac mapping.

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510(k) Summary of Safety & Effectiveness, Continued

Contra-indications

- Patients with active systemic infection.
- Patients with prosthetic valves.
- Retrograde approach in patients with aortic valve replacement.
- Transseptal approach in patients with left atrial thrombus or myxoma, or interatrial baffle patch.
- Diagnostic EP catheters are not intended for electrical ablation.

Device Description

Diagnostic electrophysiology catheters are constructed of a hollow polymer shaft approximately 92 to 125 cm in length that terminates with a hand piece or connector. A range of diameters is available; the most clinically utilized sizes are the 5 – 7 French. Various configurations of distal platinum alloy electrodes are wired to a proximal connector for bi-directional transmission of electrical signals (pacing and recording). The connector is attached to an interconnecting cable that interfaces with various standard types of sensing, recording, stimulation and pacing equipment. The catheters are available with various distal curves, either fixed or deflectable. This allows for remote manipulation of the distal tip segment that facilitates precise positioning of the electrode array.

In addition to a range of diameters, the catheters are also available in a variety of electrode configurations, connector compatibility and torque-transmitting properties that are selected by the clinician based on preference and/or indication. The shaft polymer is manufactured with additives (typically barium sulfate) that enhance the catheter's radiopacity to enable positioning under fluoroscopic guidance. No lumens of the catheters reprocessed by Vanguard are open to the patient bloodstream.

Vanguard receives previously used diagnostic EP catheters from healthcare facilities; cleans, inspects, tests, refurbishes, repackages and sterilizes the devices; and returns them to the healthcare facility.

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510(k) Summary of Safety & Effectiveness, Continued

Technological Characteristics	The Vanguard reprocessed diagnostic EP catheters are essentially identical to the currently marketed OEM devices. No changes are made to the currently marketed device's specifications and they possess the same technological characteristics. Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.
Test Data	Cleaning, sterilization and packaging validations; and functional/performance and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective.
Conclusion	Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard Reprocessed Diagnostic EP Catheters (Biosense Webster Fixed Curve and Deflectable catheters) are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 01 2002

Vanguard Medical Concepts, Inc.
c/o Mike Sammon, Ph.D.
Director, Research and Development
5307 Great Oak Drive
Lakeland, FL 33815

Re: K012687
Trade Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II (two)
Product Code: DRF
Dated: May 3, 2002
Received: May 8, 2002

Dear Dr. Sammon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 900 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Vanguard Reprocessed Diagnostic Electrophysiology Catheters

Indications for Use:

This catheter is intended for temporary intracardiac pacing and recording during electrophysiology studies, e.g. evaluation of arrhythmias or cardiac mapping.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012687